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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/597,431	09/17/2007	James Birchall	85189-13400	1867

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WINSTON & STRAWN LLP
PATENT DEPARTMENT
1700 K STREET, N.W.
WASHINGTON, DC 20006

EXAMINER

OSINSKI, BRADLEY JAMES

ART UNIT	PAPER NUMBER
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3767

NOTIFICATION DATE	DELIVERY MODE
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08/31/2010

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No. 10/597,431	Applicant(s) BIRCHALL ET AL.	
	Examiner BRADLEY J. OSINSKI	Art Unit 3767	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 July 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 3-29 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1 and 3-29 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

1. Claims 1, 3-7, 9, 10, 15-21, 23, 24, 29-31 and 36 are rejected under 35

U.S.C. 102(b) as being anticipated by Avrahami et al (2003/0208152).

a. Regarding claims 1 and 16, Avrahami discloses a method of delivering an oligonucleotide or polynucleotide via the following: generating at least one micro-channel in the skin of a subject (Paragraph 17) and applying to the skin a pharmaceutical composition of an acceptable carrier (conductive substance - Paragraph 32) with an active ingredient (Paragraph 33) of an oligonucleotide or polynucleotide (Paragraph 255). Avrahami also discloses two different subsets for generating the micro-channels (Paragraph 55-58).

b. Regarding claims 3 and 17, Avrahami specifically discloses agents based on DNA and RNA (Paragraph 257).

c. Regarding claims 4, 6, 18 and 20, insulin is specifically disclosed in paragraph 253.

d. Regarding claims 5 and 19, many different drugs are disclosed in paragraphs 234-257, including many regulatory drugs. Paragraph 253 is of particular interest.

- e. Regarding claims 7 and 21, Avrahami discloses antisense RNA (Paragraph 257).
- f. Regarding claims 9, 23 and 30, the apparatus is disclosed and has an electrode cartridge/skin patch and a main/control unit coupled to the patch that supplies electrical energy to the electrodes (Paragraph 17). This causes ablation of the stratum corneum which results in micro-channels (Paragraph 18).
- g. Regarding claims 10, 24 and 31, Avrahami does not specifically state that the micro-channels are of uniform shape and dimensions. However, the Examiner takes the position that this is implicit in the disclosure of Avrahami. Since the electrodes are not disclosed as being of differing sizes and shapes, one of ordinary skill in the art would assume they are uniform. The micro-channels are formed by the electrodes and electricity and thus since the electrodes and electricity are uniform across the device, the micro-channels will be of uniform shape and dimension.
- h. Regarding claim 15, 29 and 36, Avrahami discloses the current as having a frequency of 1 kHz to 300 kHz which overlaps with the radio frequency which is 3 kHz to 300 GHz

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 8 and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Avrahami et al (2003/0208152) as applied to claim 1 above, and further in view of Monahan et al (6,429,200).

i. Regarding claims 8 and 22, while Avrahami substantially discloses the apparatus as claimed, it does not disclose additives to the active agent such as lipids, polycations or nuclease inhibitors. However, Monahan discloses adding polycations to polynucleotides and reverse micelles in order to compact the polynucleotide which is advantageous for gene therapy (Col. 5 lines 31-54). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the delivery device/method of Avrahami to utilize polycations and reverse micelles as taught by Monahan to compact the polynucleotides for gene delivery purposes.

3. Claims 10-14, 24-28 and 31-35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Avrahami et al (2003/0208152).

j. Regarding claims 10, 24 and 31, while the Examiner believes the micro-channels are generated with a uniform shape and dimension (as stated and explained above) a backup rejection is made here. It would have been obvious to one of ordinary skill in the art at the time the invention was made to generate micro-channels of uniform shape and dimension so as to homogeneously deliver the active agent which is notoriously well known within the art as being more desirable than uneven delivery absent any other considerations.

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k. Regarding claims 11-14, 25-28 and 32-35, at the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to determine and assign diameters and lengths to the electrodes because Applicant has not disclosed that such a limitation provides an unexpected advantage, is used for a particular purpose or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with Avrahami because both Avrahami and Applicant's invention are used for the same purpose and in the same manner and also since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233 (CCPA 1955). Therefore, it would have been an obvious matter of design choice to modify Avrahami to obtain the invention as specified in claims 11-14, 25-28 and 32-35.

4. Claim 15, 29 and 36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Avrahami et al (2003/0208152) as applied to claim 9 above, and further in view of Levin et al (2005/0287217) and Avrahami (6,148,232).

l. Regarding claim 15, 29 and 36, while a word search of Avrahami does not indicate the electrical energy is specifically at 'radio frequency', a disclosure in a publication that shares a common inventor of the current application points to one of Avrahami's earlier patents (6,148,232) and shows that the device does in fact use radio frequency (Paragraph 13 of Levin et al). Therefore, it would have

been obvious to one of ordinary skill in the art at the time the invention was made to operate the device of Avrahami at radio frequency as taught by Avrahami itself in as it is a known, workable frequency for generating micro-channels.

Response to Arguments

5. Applicant's arguments filed 7-1-2010 have been fully considered but they are not persuasive. Applicant argues that Avrahami does not disclose generating micro-channels after application of an active substance. None of the claims currently claim this. There is no order inherent to method claims unless specifically claimed. While (c) comes after (b) in the claim list, it does not require that (c) has to be performed after (b). Avrahami discloses ablating the skin in two different subsets (Paragraphs 55-58).

6. Additionally, iontophoresis and electroporation, while forming smaller channels (Paragraph 18), still form channels that may be measured on the micro scale (and thus meet the claim). Avrahami discloses iontophoresis being used in conjunction with the ablation (Paragraph 63).

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not

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mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to BRADLEY J. OSINSKI whose telephone number is (571)270-3640. The examiner can normally be reached on M-Th 8AM-5PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Simons can be reached on (571)272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Bradley J Osinski/

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Examiner, Art Unit 3767

/Tatyana Zalukaeva/

Supervisory Patent Examiner, Art Unit 3761